



**PATENT**

Attorney Docket No.: A-71619/TAL/DSS

Attorney File No.: 465840-00496

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

*In re* application of:

TESI et al.

Serial No. 10/653,012

Filing Date: August 28, 2003

For: *Methods and Compositions for  
Inducing Stable Immune Tolerance*

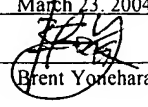
Examiner: Not Yet Assigned

Group Art Unit: 1645

CERTIFICATE OF MAILING

I hereby certify that this correspondence, including listed enclosures, is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450:

Dated: March 23, 2004

Signed:   
Brent Yorckhara

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and in accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants wish to draw the attention of the U.S. Patent and Trademark Office to the references cited on the accompanying form PTO/SB/8A. In accordance with 1273 Off. Gaz. Pat. Off. 1, 8/5/2003, no copies of U.S. patents and U.S. published applications are enclosed. Copies of all other references are enclosed.

None of the foregoing references are believed to disclose the invention as claimed. Nothing herein shall constitute an admission concerning the contents of any of the cited references, nor shall the inclusion of a reference herein be considered an admission that the reference constitutes prior art against the invention claimed in the above-identified application.

Serial No.: 10/653,012  
Filing Date: August 28, 2003

Submission of the present document shall not be construed as an admission that a search has been made or that better art does not exist.

As far as is known to the undersigned, this Information Disclosure Statement is being filed within three months of the filing date of a national application, within three months of the date of entry of the national state in an international application, or before the mailing date of a first Office Action on the merits as set forth in 37 C.F.R. § 1.97(b), and therefore no fee is required.

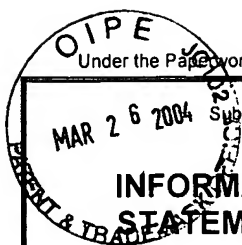
While no further fee is believed to be due, if this belief is in error, the Commissioner is authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-2319 (Our Order No. 465840-00496 (A-71619/TAL/DSS)).

Respectfully submitted,

DORSEY & WHITNEY LLP

Dated: 3/22/04  
**Customer Number: 32940**  
Dorsey & Whitney LLP  
Intellectual Property Department  
Four Embarcadero Center, Suite 3400  
San Francisco, CA 94111-4187  
(415) 781-1989 (telephone)  
(415) 398-3249 (facsimile)

By:   
~~Todd A. Lorenz, Reg. No. 39,754~~



Substitute for form 1449A/PTO

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

## **Complete if Known**

Sheet	1	of	3	Application Number	10/653,012
				Filing Date	August 28, 2003
				First Named Inventor	TESI, Raymond J.
				Group Art Unit	1645
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	A-71619/TAL/DSS (465840-496)

## **U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	5,135,934	08-04-1992	Behrens et al.	
	A2	5,167,956	12-01-1992	Neville et al.	
	A3	5,204,329	04-30-1993	Ackerman et al.	
	A4	5,428,040	06-27-1995	Magolda et al.	
	A5	5,476,870	12-19-1995	Renault et al.	
	A6	5,523,408	06-04-1996	Batt et al.	
	A7	5,637,613	06-10-1997	Renault et al.	
	A8	5,725,857	03-10-1998	Neville et al.	
	A9	5,733,928	03-31-1998	Lebreton et al.	
	A10	5,762,927	06-09-1998	Knechtle et al.	
	A11	5,856,487	01-05-1999	Upadhyay et al.	
	A12	5,883,132	03-16-1999	Lebreton et al.	
	A13	5,916,910	06-29-1999	Lai	
	A14	6,093,743	07-25-2000	Lai et al.	
	A15	6,103,235	08-15-2000	Neville et al.	
	A16	6,140,363	10-31-2000	Hur et al.	
	A17	6,204,243	03-20-2001	Posanski	
	A18	6,245,781	06-12-2001	Upadhyay et al.	
	A19	6,291,483	09-18-2001	Upadhyay et al.	
	A20	6,407,135	06-18-2002	Lai et al.	
	A21	6,503,883	01-07-2003	Posanski	
	A22	6,645,970	11-11-2003	Albert et al.	
	A23	6,649,591	11-18-2003	Lai	

## **FOREIGN PATENT DOCUMENTS**

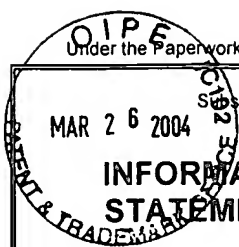
Examiner Initials*	Cite No.	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	B1					

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.

The collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2.0 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents,

P.O. Box 1450, Alexandria, VA 22313-1450.1134045\_1



Substitute for form 1449A/PTO

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

## **Complete if Known**

Application Number	10/653,012
Filing Date	August 28, 2003
First Named Inventor	TESI, Raymond J.
Group Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	A-71619/TAL/DSS (465840-496)

Sheet

2

of

3

## **NON PATENT LITERATURE DOCUMENTS**

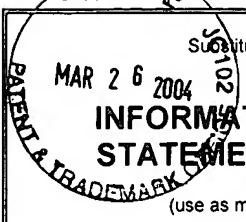
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	C1	BANCHEREAU, J., et al., "Dendritic cells and the control of immunity," <i>Nature</i> 392(6673):245-252 (Mar. 1998).	
	C2	BUTTURINI, A., et al., "T cell depletion in bone marrow transplantation," <i>Bone Marrow Transplant.</i> 3(3):185-192 (May 1988).	
	C3	CHIFFOLEAU, E., et al., "Role for thymic and splenic regulatory CD4+ T cells induced by donor dendritic cells in allograft tolerance by LF15-0195 treatment," <i>J. Immunol.</i> 168(10):5058-5069 (May 2002).	
	C4	CONTRERAS, J.L., et al., "Peritransplant tolerance induction with anti-CD3-immunotoxin: a matter of proinflammatory cytokine control," <i>Transplantation</i> 65(9):1159-1169 (May 1998).	
	C5	GHANEKAR, A., et al., "Treatment with rabbit antithymocyte serum permits a cyclophosphamide-free approach to prevention of hDAF transgenic porcine kidney xenograft rejection in baboons," <i>Transplant Proc.</i> 33(7-8):3849-3850 (Nov.-Dec. 2001).	
	C6	HARIHARAN, S., et al., "Improved graft survival after renal transplantation in the United States, 1988 to 1996," <i>New Eng. J. Med.</i> 342(9):606-612 (Mar. 2000).	
	C7	HAYAMIZU, K., et al., "Donor cells that facilitate tolerance to rat heart allografts after posttransplant total lymphoid irradiation and rabbit anti-thymocyte globulin," <i>Transplant Proc.</i> 31(3B Suppl):25S-26S (May 1999).	
	C8	HUBBARD, W.J., et al., "Phenotypic and functional analysis of T-cell recovery after anti-CD3 immunotoxin treatment for tolerance induction in rhesus macaques," <i>Hum. Immunol.</i> 62(5):479-487 (May 2001).	
	C9	KIRK, A.D., "Transplantation tolerance: a look at the nonhuman primate literature in the light of modern tolerance theories," <i>Crit. Rev. Immunol.</i> 19(5-6):349-388 (1999).	
	C10	KNECHTLE, S.J., et al., "Inducing unresponsiveness by the use of anti-CD3 immunotoxin, CTLA4-Ig, and anti-CD40 ligands," <i>Transplant Proc.</i> 31(3B Suppl):27S-28S (Nov.-Dec. 1999).	
	C11	LI, Y., et al., "Blocking both signal 1 and signal 2 of T-cell activation prevents apoptosis of alloreactive T cells and induction of peripheral allograft tolerance," <i>Nat. Med.</i> 5(11):1298-1302 (Nov. 1999).	
	C12	LIBBY, P., et al., "Chronic rejection," <i>Immunity</i> 14(4):387-397 (Apr. 2001).	
	C13	NEUHAUS, P., et al., "mTOR inhibitors: an overview," <i>Liver Transplant.</i> 7(6):473-484 (Jun. 2001).	
	C14	NEVILLE, D., et al., "A new reagent for the induction of T-cell depletion, anti-CD3-CRM9," <i>J. Immunother. Emphasis Tumor Immunol.</i> 19(2):85-92 (Mar. 1996).	
	C15	ODAKA, C., et al., "Immunosuppressant deoxyspergualin induces apoptic cell death in dividing cells," <i>Immunology</i> 95(3):370-376 (Nov. 1998).	
	C16	THOMAS, F.T., et al., "15-Deoxyspergualin: a novel immunosuppressive drug with clinical potential," <i>Ann. NY Acad. Sci.</i> 685:175-192 (Jun. 1993).	
	C17	THOMAS, J.M., et al., "Peritransplant tolerance induction in macaques: early events reflecting the unique synergy between immunotoxin and deoxyspergualin," <i>Transplantation</i> 68(11):1660-1673 (Dec. 1999).	
	C18	THOMAS, J.M., et al., "STEALTH matters: a novel paradigm of durable primate allograft tolerance," <i>Immunol. Rev.</i> 183:223-233 (Oct. 2001).	
	C19	THOMAS, J.M., et al., "Successful reversal of streptozotocin-induced diabetes with stable allogeneic islet function in a preclinical model of type 1 diabetes," <i>Diabetes</i> 50(6):1227-1236 (Jun. 2001).	

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.

The collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2.0 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents,

P.O. Box 1450, Alexandria, VA 22313-1450.1134045\_1

 <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)</p>			<b>Complete if Known</b>		
			Application Number	10/653,012	
			Filing Date	August 28, 2003	
			First Named Inventor	TESI, Raymond J.	
			Group Art Unit	1645	
			Examiner Name	Not Yet Assigned	
Sheet	3	of	3	Attorney Docket Number	A-71619/TAL/DSS (465840-496)

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	<sup>6</sup>
	C20	UMEZAWA, H., et al., "Suppression of tissue graft rejection by spargualin," <i>J. Antibiot. (Tokyo)</i> 38(2):283-284 (Feb. 1985).	
	C21	WELLS, A., et al., "Requirement for T-cell apoptosis in the induction of peripheral transplantation tolerance," <i>Nat. Med.</i> 5(11):1303-1307 (Nov. 1999).	
	C22	WU, G., et al., "Effect of plasma exchange in combination with deoxyspergualin on the survival of guinea-pig hearts in macrophage-depleted C6-deficient rats," <i>Xenotransplantation</i> 10(3):214-222 (May 2003).	

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.

The collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2.0 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents,

P.O. Box 1450, Alexandria, VA 22313-1450.1134045\_1